



MAMSS 32nd Annual Education Conference

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Legal Update

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LEGAL UPDATE:

Final Medicare Medical Staff Conditions of Participation: What Should be in your Bylaws

Areas To Be Covered

- Hospital Governing Board
 - Do physicians have to serve on boards?
 - How must board consult with the organized medical staff if physicians are not on the board?
- Hospital Medical Staff – Membership
 - What practitioners can be appointed as members of the medical staff?
 - Must membership be expanded if permitted under state law?
- Hospital Medical Staff – Separate or Unified?
 - Overview of options to create a single, unified and integrated medical staff in a multi-hospital system.

Areas To Be Covered (cont'd)

- How must the Board interact with staff at each hospital?
- What is the medical staff voting process and who can vote?
- Must members in a unified medical staff have the option to create a separate medical staff?
- What impact on bylaws?
- What if the staffs serve different patient populations and have other unique circumstances?
- Ordering Hospital Outpatient Services
 - Who can order?

Hospital Governing Board

- Background

- On May 16, 2012, CMS published a final rule that allowed one governing board to oversee multiple hospitals in a multi-hospital system.
- If there is one board but there are separately certified hospitals, each must demonstrate compliance with the Medicare CoPs.
- Rule also required that a medical staff member or members from at least one of the hospitals be included on the board.
- Many hospitals responded that the rule created complications, especially for public hospitals where local rules or state statutes required board members to be publicly elected or appointed by a government official.

Hospital Governing Board (cont'd)

- Final Rule and CMS September Guidance
 - Hospitals are not required to have physician board members.
 - If hospital chooses this option, it must:
 - Consult directly with the individual who is assigned the responsibility for the organization and conduct of the medical staff – probably the medical staff president.
 - “Direct consultation” means that the board or a subcommittee meets either face-to-face or via a live telecommunications system.

Hospital Governing Board (cont'd)

- Consultations must occur periodically, but at least twice a year.
- Must include discussions related to quality of patient care provided at the hospital, such as specific population needs, scope and complexity of hospital services and development of performance improvement standards.
- In a multi-hospital system, consultations must be with the responsible physician of each hospital medical staff.
- Hospital must evidence and document that it has been appropriately responsive to requests from medical staff representative regarding quality of care issues.

Hospital Governing Board (cont'd)

- In a multi-hospital system, the requirement can be met by means other than a separate meeting with the representative from each hospital medical staff, such as through a committee structure and teleconferencing BUT issues for each hospital must be addressed.
- If medical staff members have opted for a unified staff, the board can meet with leader of the medical staff to fulfill this requirement, but the leader needs to be aware of the concerns or views of members practicing at each separately certified member hospital.
- Requirement can be met if there is a medical staff representative on the board if
 - the representative or his/her designee is responsible for the organization and conduct of the hospital's medical staff
 - there are periodic meetings to discuss matters of the quality of medical care delivered at the hospital.
- Boards clearly can have more than one physician member.

Hospital Governing Board (cont'd)

- Impact and Recommendations

- If the entity is not a public hospital or other hospital which requires election or appointment to board by a government official, then best practice is to have medical staff representation.
- Based on the description of the responsible physician, appointment of the president of the medical staff will meet this requirement.
- “Direct consultation” is still required whether or not there is medical staff representation on the board.
- Hospital must document that these consultations occurred—such as minutes, agenda, parties present—and that matters related to the quality of patient care were discussed.

Hospital Governing Board (cont'd)

- Must decide whether to utilize full board or a board committee.
- In a multi-hospital system, depending on the number of hospitals, a committee approach could be utilized, whether by region or state or as a whole, but could be difficult to manage given divergent issues, different patient population and other unique factors.
- Board or board committee could be split up to meet with medical staff representatives.

Hospital Governing Board (cont'd)

- Decide which committee best suits this requirement.
- Will likely need to modify both the corporate and medical staff bylaws depending on course of action.
- Can adopt uniform bylaws or policies across multi-hospital system, but must specifically reference each participating hospital.
- Minutes of governing body must be written so that its actions apply to a specific certified hospital.

Hospital Governing Board (cont'd)

- Departments of separately certified hospitals with a single board cannot be operated in an integrated manner. For example, each must have its own nursing service.
- Policies can be identical but services have to be separate.
- There must be a specific QAPI program for each program but can use same quality indicators or method to track adverse events – need specific hospital results.

Hospital Medical Staff - Membership

- Background
 - The May 16, 2012 final rule on the permitted composition of the medical staff was confusing with regard to the use of “non-physician practitioners” because it inadvertently excluded other practitioners from medical staff membership.
 - The requirement that the medical staff must include DOs and MDs also suggested that other practitioners were excluded even if they met the state’s definition of “physician.”

Hospital Medical Staff – Membership

(cont'd)

■ Final Rule

- The medical staff must be composed of MDs and DOs.
- In accordance with state law, including scope of practice laws, the medical staff may also include other categories of physicians, i.e., dentists, podiatrists, and non-physician practitioners, who also are determined to be eligible by the board, i.e., APNs, PAs.

■ Impact and Recommendations

- Hospitals are not required to put anyone other than MDs and DOs on the medical staff, even if permitted to do so under state law.
- Consider expanding membership if permitted under state law.

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Hospital Medical Staff – Membership

(cont'd)

- Board has final say on which categories of physician and non-physician practitioners are entitled to medical staff membership.
- Even if not allowed to be a member of the medical staff, practitioners can be given clinical privileges as long as they are credentialed and privileged in accordance with the applicable bylaws and policies and the privileges granted are within the scope of permitted practice under state law and as approved by the board.

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Hospital Medical Staff – Unified Integrated Staff

- Background
 - Previous rule required that each hospital must have a separate medical staff for each separately certified hospital in a multi-hospital system.
 - Because the rule was somewhat ambiguous, a number of multi-hospital systems created a unified and integrated staff.
 - Many of the comments received by CMS from individual physicians as well as state and national physician organizations strongly supported the separate medical staff rule and urged CMS to reinforce the standard and clarify the ambiguity.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- The concern expressed was that the concept of “self governance” under TJC standards would be destroyed and that individual autonomy and local concerns and issues at the hospital would be ignored or not adequately addressed in a unified medical staff.
- On the other hand, most hospitals and health systems supported the option of creating a unified and integrated staff. One unidentified Commentator reported that the model “substantially contributed to our success as an integrated delivery system and has accelerated our quality, safety, and efficiency performance.”
- As additional support for this claim, it identified significant improvements in lowering in-hospital mortality rates and readmission rates and it had the second lowest congestive heart failure readmission rates in the nation based on published CMS data.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Final Rule
 - Medical staff members of each separately certified hospital in a multi-hospital system must have voted in the majority, in accordance with the bylaws, either to accept or opt out of a unified and integrated staff structure for their hospital.
 - Board must also agree to a unified and integrated staff.
 - Unless otherwise stated in bylaws, this means a majority of those physician members eligible to vote.
 - Telemedicine physicians are not eligible to vote.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- A unified staff has one set of bylaws, rules and requirements that describe its processes for self-governance, appointment, credentialing, privileging, oversight, peer review, and hearing rights as applied to all members of the unified staff; and a process for advising them in writing of their right to opt out.
- The unified staff must be established in a manner which takes into consideration each member hospital's unique circumstances and any significant differences in patient populations and services offered at each hospital.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- The unified staff:
 - Establishes and implements policies and procedures to ensure that the needs and concerns expressed by medical staff members at each hospital are given due consideration.
 - Mechanisms must be in place to ensure that issues localized to particular hospitals are considered and addressed.
- Separately certified hospitals that share a single integrated staff must also share one governing body.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- A multi-campus hospital is not a multi-hospital system and therefore can only have one medical staff and not separate staffs at each hospital.
- The option to use a single unified staff has to be permitted under state law.
- The choice of whether to opt in or opt out of a single unified staff in a multi-hospital system is not an all-in or all-out option. The system can have staffs which have made different choices.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- A system which had a unified medical staff prior to July 11, 2014, when the standard became effective, will serve as evidence of its election to approve this structure – no new vote is required (the standard assumes a prior vote took place).
- For a system that had a unified staff prior to July 11, 2014, bylaws need to be amended within six months to reflect requirements of §482.22(b)(4)(i-iv). Nothing precludes the ability to conduct a vote prior to completion of bylaw amendments.
- All system governing bodies which select this option, whether before or after July 11, 2014, must still review and document that this election was made and that the decision does not conflict with state or local laws or regulations.
 - CMS surveyors will request this documentation.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Must also inform medical staff members of their right to opt out.
- Privileges given to practitioners need to be specific to each practitioner and to each hospital where he or she exercises privileges and the services offered there.
- Process for medical staff to opt in or opt out must be in the bylaws of all system hospitals, even hospitals where the medical staff is not participating in a unified staff.
- Depending on state law, the unified medical staff bylaws, rules and regulations can be in addition to or a substitute for hospital-specific ones, but cannot conflict.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Medical staff and board has the flexibility of determining the details of the voting process.
 - How the opt-in or opt-out vote can be requested.
 - What categories of membership holding privileges to practice onsite can vote.
 - Whether voting will be in writing and by open or secret ballot.
 - Method cannot be more restrictive than currently afforded under bylaws when considering and voting on amendments—i.e., it cannot require approval by two-thirds of voting members if only a majority is required.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Cannot require as a condition of opting out a petition signed by the same number of voting members as would be required for a successful opt-out vote.
- When a hospital system has a unified medical staff and a medical staff has exercised its right to hold a vote on opting out, the decision cannot be delegated solely to the unified medical executive committee, even if the MEC is otherwise given this authority for other matters pursuant to the bylaws. Eligible members must still be able to vote. Must be approved by a majority.
 - But if the system has a separate medical staff and is voting on whether to opt in to a unified staff, the vote can be made by the MEC if bylaws give it this right at the time of the vote.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Minimal intervals between consideration of an opt-in or opt-out vote can be established but cannot be longer than two years.
- Guidance does not say whether Board has the right to veto or not accept opt-out vote.
- Policies and Procedures
 - Given the likely differences between system hospitals, the expectation is that these differences and the varying needs will be reflected in the policies and procedures of each hospital.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- There can be system wide standards, but they must reflect uniqueness of each facility where appropriate.
- Data collected and results (for example, for the QAPI program) must be hospital-specific.
- Must have written policies and procedures in place that address how the unified staff addresses needs and concerns of its practicing members relating to patient needs and healthcare quality.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Written policy must cover:
 - A process for raising local concerns and needs
 - How members are informed about the process
 - A process for referring concerns and needs to an appropriate committee
 - Must document outcome

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Impact and recommendations
 - Only those hospitals which have a common governing board that privileges, credentials, appoints and reappoints members of each medical staff are eligible to consider the single integrated medical staff option.
 - No Bylaw amendments are necessary unless the Board approves this option after first determining whether it is permitted under state law. This determination must be documented.
 - If the Board approves this option, the bylaws committee should be convened to develop process and amendments as soon as possible.
 - Must also develop policies as per CoP requirements, but need to follow internal development and approval procedures.

Hospital Medical Staff – Unified Integrated Staff (cont'd)

- Documentation of compliance with requirements are extremely important. Written notice of opt-in or opt-out rights should be placed in physician's credentials file.
- Questions as to whether to create a unified staff or to participate in one should take place between leaders of the medical staff and hospital using an existing committee with joint membership, or an ad hoc committee to determine level of interest/disinterest.
- Need to determine impact on Medicare reimbursement if moving toward single governing body and single CCN member.

Ordering Outpatient Services

- Background
 - The goal of the November 18, 2011 final version of the Interpretive Guideline was to expand the categories of practitioners who could order rehab, respiratory and other outpatient services, but the requirement that they also had to have medical staff privileges at the hospital had the opposite effect.
 - Many practitioners who place these orders are not on the hospital's medical staff and sometimes are located in different geographic markets and states.

Ordering Outpatient Services (cont'd)

- Final Rule
 - Outpatient services must be ordered by a practitioner who meets the following conditions:
 - Is responsible for the care of the patient
 - Is licensed in the state where he or she provides care to the patient
 - Is acting within his or her scope of practice under state law
 - Is authorized in accordance with state law and policies adopted by the medical staff and approved by the board to order the applicable outpatient services.

Ordering Outpatient Services (cont'd)

- Standard applies to:
 - All practitioners on the medical staff who have been given privileges to order the applicable services
 - All practitioners not on the medical staff but who satisfy the eligibility criteria.
- Impact and recommendations
 - Need to decide what categories of practitioners and what outpatient services each category can order consistent with that state's scope of practice statutes.
 - Would need to check statutes first if allowing out of state practitioners to order services.

Resource List

- Revised CMS final rule:
www.federalregister.gov/articles/2014/05/12/2014-10687/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and#h-19
- CMS Interpretive Guidelines:
www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R122SOMA.pdf

THE NEW NPDB GUIDEBOOK

NPDB Background

- In 1987, Congress authorized federal government to collect sanctions information taken by state licensing authorities against health care practitioners and health care entities.
- Patrick v. Burget (1988)
 - U.S. Supreme Court reversed a Circuit Court of Appeals decision which had found that the state action doctrine exempted peer review conduct from antitrust liability.
 - The effect of the decision was to reinstate a civil judgment against physicians on a on a medical staff for their “bad faith” peer review.
 - In response to concerns that physicians would not participate in peer review activities and that incompetent physicians were moving from state to state to avoid detection in 1990, the law was amended to add any negative findings by peer review or accreditation entities.

NPDB Background (cont'd)

- In 1999, final regulations passed leading to the formation of the health care Integrity and Protection Data Bank (“HIPDB”) which received and disclosed certain final adverse actions, such as licensure, certification, criminal and civil convictions and exclusions from state and federal health care programs based on health care fraud and abuse violations.
- In 2013, NPDB and HIPDB operations were consolidated.

Hospital Obligation to Query (cont'd)

- APNs
 - Yes if on the medical staff or if granting them clinical privileges
- Emeritus, Honorary Members
 - Yes if on the Medical Staff even if not exercising clinical privileges.
- What if hospital fails to query?
 - Hospital will be presumed to be aware of NPDB information

Eligible Entities that Report to and Query the NPDB (cont'd)

- Hospitals – required to report and query.
- Other health care entities – optional.
 - Must provide health care services.
 - Must follow a formal peer review process to further quality health care.
 - Is broad in scope and **can** apply to HMOs, PPOs, group practices, nursing facilities, patient centered medical homes and ACOs.
 - If it provides health care services and performs peer reviews for the purpose of furthering health care, it must report and may query at any time.

Reporting Requirements and Query Access (cont'd)

- **Question:** Can eligible entities report on health care practitioners who are not physicians or dentists?
 - **Yes**

Hospital Obligation to Query

- When a physician, dentist or other health care practitioner applies for medical staff appointment **or** for clinical privileges at the hospital, including temporary privileges at **each** request including locum tenens.
- Reappointment every two years.
- When a practitioner seeks to add or expand existing clinical privileges.
- Residents and interns (house staff)
 - **No** if exercising privileges pursuant to a formal educational program.
 - **Yes** if exercising clinical privileges outside educational programs, i.e., moonlighting in ICU or ED.
 - **Yes** if being appointed to the medical staff or if granting them clinical privileges.

What if Hospital Fails to Query?

- Hospital will be presumed to be aware of NPDB information.
- A plaintiff's attorney or plaintiff representing him or herself will have access to information for use in litigation against the hospital. Needs to submit:
 - Evidence that an actual malpractice action or claim has been filed by the plaintiff against the hospital.
 - Letter requesting authorization to obtain information.
 - Supporting evidence that hospital did not make mandatory query regarding defendant physician/practitioner.
 - Identifying information about practitioner.
 - Allowed a one-time disclosure at the time hospital was required to query.

Centralized Credentialing

- If health care system has multiple qualifying health care entities at which a practitioner is allowed to exercise membership and/or clinical privileges only one query needs to be made if using a centralized peer review process and one decision making body.
- If each entity conducts its own credentialing and only grants membership/privilege at its site then query response cannot be shared and separate queries must be made.

Delegated Credentialing

- A health care entity that delegates its credentialing responsibilities to another entity is prohibited from receiving NPDB querying results, i.e., a PHO which delegates to a hospital.
- Different from use of an authorized agent who simply queries and receives information on behalf of the entity, i.e., hospital is an authorized agent of PHO.
- Authorized agents cannot use a query response on behalf of more than one entity.
- If two separate entities choose the same authorized agent and are making a query on the same individual, agent must make two separate queries. Information cannot be shared — would violate confidentiality requirements.

Delegated Credentialing (cont'd)

- **Question**: Can NPDB report be shared including use in a hearing and appeal process?
 - **Yes** as long as the individuals are part of the credentialing/privileging/peer review/hearing process.

Delegated Credentialing (cont'd)

- **Question**: Can a hospital share an NPDB report with an unrelated health care entity if authorized to do so by the practitioner?
 - **No** if not a part of the hospital's investigation or peer review process.

Time Frame for Reporting

Table E-2: Time Frame for Reporting

Types of Actions that Must Be Reported	When Information Must be Reported
<p>Medical malpractice payments</p> <p>Certain adverse licensure actions related to professional competence or conduct (reported under Title IV)</p> <p>Certain adverse professional society membership actions related to professional competence or conduct</p> <p>Certain adverse professional society membership actions related to professional competence or conduct</p> <p>DEA controlled-substance registration actions or practitioners (reported under Title IV)</p> <p>Exclusions from participation in Medicare, Medicaid, and other Federal health care programs (reported under Title IV)</p>	<p>Within 30 days of the date the action was taken or the payment was issued, beginning with actions occurring on or after September 1, 1990</p>
<p>Negative actions or findings taken by peer review organizations</p> <p>Negative actions or findings taken by private accreditation organizations</p>	<p>Within 30 days of the date the action was taken, beginning with actions occurring on or after January 1, 1992</p>
<p>State Licensure and certification actions</p> <p>Federal licensure and certification actions</p> <p>Health care-related criminal convictions in Federal or State Court</p> <p>Health care-related civil judgments in a Federal or State health care program</p> <p>Other adjudicated actions or decisions</p>	<p>Within 30 days of the date the action was taken, beginning with actions occurring on or after August 21, 1996</p>

Types of Reports

- Initial Report
 - Affected practitioner receives a copy.
 - Report needs to be factually accurate.
- Correction Report
 - Submitted when error identified.
 - Replaces the original Initial Report.
 - Practitioner receives a copy and sends also to any person or entity who queried and received a copy of the erroneous report in the past three years.

Types of Reports (cont'd)

- Hospital also needs to send the corrected report to the appropriate state licensing board or certification authority.
- Void Report
 - A report submitted in error or if action was not reportable or action overturned on appeal.
 - Notification sent to practitioner and any person or entity which received previous report during past three years.
 - Void Report removed from record.

Types of Reports (cont'd)

- Revision-to-Action Report
 - Is a report which modifies but does not replace the Initial Report. Both become part of the discloseable record. Examples include:
 - Initial 90 day suspension reduced to 45 days.
 - State medical boards decision to reprimand physician changed to a probation when physician fails to complete required continuing education credits.

Narrative Descriptions

- “Must include sufficient detail to ensure future queriers have a clear understanding of what the subject of the report is alleged to have done and the nature of the event upon which the report is based.”
- Should be limited to the official findings or facts of the case.
- Include a description of the circumstances leading to the action taken.
- Should consult with legal counsel before filing.
- NPDB reserves the right to determine that description does not provide sufficient detail which would then require a Correction Report. If report not submitted NPDB will treat this as a failure to report. [New]

Narrative Descriptions (cont'd)

- **Question**: May a reporting organization provide a copy of the NPDB report to the practitioner?
 - **Yes**, but ~~identifying information should be removed.~~ NPDB automatically sends instructions on how to get an official copy. [Deleted]

Reporting Adverse Clinical Privileges Actions

- Decisions must be based on a physician's or dentists professional competence or conduct that adversely affects, or could adversely affect, the health or welfare of a patient.
- Decision is made by the reporting health care entity.
- Reporting non-physicians is optional.

When Are The Actions Reportable?

- Professional review actions that adversely affect a physician's or dentist's clinical privileges for more than 30 days.
- Acceptance of surrender or restriction of clinical privileges while under investigation or in return for not conducting such an investigation or not taking a professional review action that otherwise would be required to be reported to the NPDB.
- Adverse actions include:
 - Reducing
 - Restricting
 - Suspending
 - Revoking
 - Non-renewal of membership/privileges based on professional competence or conduct.

When Are The Actions Reportable? (cont'd)

- **Question:** What is a professional review action that relates to professional competence or conduct that adversely affects or could adversely affect the health or welfare of a patient?
 - Defined as “an action or recommendation of a health care entity taken in the course of professional review activity.”
 - A “professional review activity” is an “activity of a healthcare entity with respect to an individual health care provider to determine” whether they may have clinical privileges or membership, the scope or conditions or to change or modify scope.
 - Appears that entity has some flexibility in deciding what does and what does not constitute a professional review action.

When Are The Actions Reportable? (cont'd)

- Draft states that censures, admonishments and reprimands greater than 30 days are reportable.
 - WRONG – Physician privileges are not adversely affected by these decisions. Same for monitoring, practicing and mandatory consultations – This reference was deleted.
- Decisions based on failure to pay dues, failure to maintain insurance, employment disputes or other business issues are **not** reportable.
- Revocations based on failure to become board certified or some other similar eligibility criteria are **not** reportable.
- If multiple adverse actions taken which are each otherwise reportable, only one report is required but should use narrative description to explain all actions taken.

When Are The Actions Reportable? (cont'd)

- **Question**: If a physician's initial application or request for expanded privileges is denied, is this decision reportable?
 - Depends on whether the decision was the product of a professional review action based on clinical competency or simply that physician did not satisfy eligibility criteria.
 - Example: Physician did not have appropriate experience to obtain specialized surgical privileges beyond core privileges – not reportable.
 - Example: Did not have minimum number of cases – not reportable.

When Are The Actions Reportable? (cont'd)

- **Question**: If a physician's privileges are automatically terminated because his license was revoked, is this decision reportable?
 - **No** because there was no professional review action

When Are The Actions Reportable? (cont'd)

- **Question**: If an employed physician is terminated based on professional competency issues, is the termination reportable?
 - **Yes** if there was a professional review action, which rarely takes place. **No** if there was not.

Withdrawal of Applications

- Voluntary withdrawal of an initial application prior to a final professional review action generally not reportable.
- If application is withdrawn at time of reappointment while under investigation for incompetence or improper professional conduct or in return for not conducting an investigation or taking professional review action then withdrawal is reportable.
- Denial of application and application withdrawal reportable even if physician had no knowledge of the investigation.
 - Many commentators objected to this statement as being inherently unfair but NPDB did not change its position.
 - Data Bank on record as stating that physician's misleading or false representations on an initial application is reportable if accurate information would have led to a denial.

Investigations

- Routine investigations are not reportable.
- Surrender or restriction of privileges while under investigation or to avoid an investigation is reportable.
- “NPDB interprets the word ‘investigation’ expansively.”
- Will look at bylaws and other document to assist in determining whether an investigation was triggered or is ongoing “but [NPDB] retains the ultimate authority to determine whether an investigation exists.”
- “An investigation begins as soon as the health care entity begins an inquiry and does not end until [the hospital] takes a final action or makes a decision to not further pursue the matter.”

Investigations (cont'd)

- “Must concern the professional competence and/or conduct of the practitioner.”
- Activity should be a precursor to a professional review action.”
- OPPEs not reportable because the standards apply for everyone.
 - “If the formal peer review process is used when issues relating to competence or conduct are identified or when a need to monitor a physician’s performance is triggered based on a single event or pattern of events ... this is considered an investigation for the purposes of reporting to the NPDB.” (E31) – This reference to monitoring was dropped from the final Guidebook.

Investigations (cont'd)

- Should have documented evidence of an investigation if reporting a surrender of privileges such as minutes, orders, notices.
- “An investigation is not limited to a health care entity’s gathering of facts. An investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity’s decision making authority takes a final action or formally closes an investigation.”

Investigations *cont'd*

- The NPDB's position on what constitutes an investigation for reporting purposes, including the determination that an FPPE is an investigation, was universally criticized by such organizations as The Joint Commission, NAMSS, AHA and the NPDB Guidebook Work Group. Comments include the following:
 - The use of OPPEs and FPPEs was established to TJC to help serve as “part of a continuous process of evaluation to ensure a high quality and safe health care system.”
 - Hospitals required to impose an FPPE on all new applications— does not mean they are under an investigation.
 - Characterization of an FPPE as an investigation might lead a hospital and medical staff to avoid using FPPEs.

Investigations *cont'd*

- Hospital and medical staff should be able to define what constitutes an investigation in their bylaws consistent with the statute and regulations.
- Peer review activities should not be characterized as investigation.
- Imposition of an FPPE does not typically trigger hearing rights and therefore a hospital would almost be required to provide a hearing if it wants to access the immunity protections under HCQIA.

Investigations *cont'd*

- Investigations are more typically triggered when there is a formal request for corrective action by the MEC or hospital. The reviews and analyses which take place before this request including OPPE/FPPEs are viewed as normal, routine peer review activity.
- If imposition of a FPPE plan is not reportable neither should resignation before or after imposition of an FPPE plan – privileges are not limited.

Summary Suspensions

- Are reportable if in effect for more than 30 days even though there is no final decision.
- Should be limited to where action is needed to protect patients from “imminent danger”.
- Determine if some lesser form of remedial action will suffice.
- Hearing panels oftentimes overturn summary suspensions.
- Consider requiring that at least two individuals, one clinician and one administrator, must concur before imposing

Summary Suspensions *cont'd*

- If suspension is reversed or modified then appropriate report needs to be submitted such as a Void Report or a Reversion-to-Action.
- Use if different terms, i.e., emergency, precautions immediate, makes no difference.

Proctoring/Monitoring/Mandatory Consultations

- Imposition of a monitoring/proctoring/mandatory consultation is **not** reportable because physician can still exercise clinical privileges.
- If a Department Chair or other individual must approve a procedure or has veto authority then action **is** reportable.

Sanctions for Failing to Report

- Can lose the Health Care Quality Improvement Act immunity protections for 3 years.
- Health care entity, if it is determined to have substantially failed in reporting an adverse decision, will be given an opportunity to either comply without a penalty or to request a hearing.

LEGAL UPDATE:

Tibbs v. Bunnell

Legal Update – Tibbs v. Bunnell (cont'd)

- University of Kentucky filed a Motion and Petition for Rehearing for the purpose of remanding the case back to the Appellate Court because the statutory construction argument was never presented to the trial and Appellate Court and therefore was never addressed by the parties.
- This Petition was supported in separate motions by the AHA, AMA, The Joint Commission and over 30 other amicus parties along with additional arguments as to how the Court erred. These include the following:
 - Court did not correctly interpret Congress's intent as to the full scope of the Patient Safety Act's protections.

Legal Update – Tibbs v. Bunnell (cont'd)

- PSA does not preclude a hospital from collecting and maintaining incident reports within its PSES unless required to submit these reports to the state or federal government.
- Court glossed over the fact that Kentucky does not require these incident reports to be reported to the state.
- While information collected outside the PSES cannot be protected, the report in question clearly was collected and maintained in UK's PSES.
- The fact that a state mandated the establishment, collection and maintenance of a record does not automatically mean it cannot be accomplished within a PSES – it can be dropped out later and reported if required.

Legal Update – Tibbs v. Bunnell (cont'd)

- Even if a mandated report was incorrectly reported to a PSO, the hospital cannot disclose unless it specifically authorizes disclosure consistent with the PSA requirements.
- If not disclosed, the hospital runs the risk of being cited, fined or otherwise penalized unless it can otherwise demonstrate compliance with state/federal laws.
 - Neither CMS nor TJC requires a PSO or provider to turn over PSWP.

Legal Update – Tibbs v. Bunnell (cont'd)

- The Amicus motions were denied, as was UK's Petition.
- UK has since filed the petition for a Writ of Certiorari to the United States Supreme Court on March 18.
- Amicus briefs will be filed by numerous PSOs, the AHA, AMA, and The Joint Committee, which are due April 17.
- What Legal Impact Does Tibbs Have?
 - If the U.S. Supreme Court agrees to review Tibbs, the decision likely will have a national impact on all PSOs and providers.
 - If decision is not reviewed, it is only binding on courts, PSOs, and providers located in Kentucky and no other state.

Legal Update – Tibbs v. Bunnell (cont'd)

- There are still procedural issues and potential discovery disputes being played out in the Tibbs case and therefore the final outcome on what information ultimately needs to be produced has not been determined.
- Once issue that has been raised is whether AHRQ/OCR would fine UK if it turned over the report – could serve as a vehicle to get into federal court because you would have a state court decision conflicting with a federal statute and potential agency action.
- A concern is that the wrong analysis in Tibbs could be embraced by other courts looking for a way to limit the PSA protections, but keep in mind trial court decisions in other jurisdictions are only binding on the parties involved in the litigation
 - Southern Baptist Hospital of Florida, Inc. v. Charles (This case is currently before the Florida Appellate Court. Case goes further by also contending that information which a provider is required to collect and maintain, not only under state law, but federal law and accreditation standards to not be PSWP.)

Legal Update – Tibbs v. Bunnell (cont'd)

- Should PSOs/Hospitals limit scope of what to collect in their PSES consistent with Tibbs decision?
 - No!
 - These issues/disputes will be decided in each state. The only binding decisions in your state affecting state versus federal claims are decisions issued by state supreme court or appellate courts – not trial courts.
- Reminders
 - In a state with mandated reporting only provide what is minimally required – limit reports to the facts if permitted.

Legal Update – Tibbs v. Bunnell (cont'd)

- What you are not required to report to the state (or federal government) can be collected in your PSES and reported to the PSO.
- To protect against a Tibbs analysis consider re-titling reports. In other words, the patient incident report you may be required to collect and maintain under state law can be limited to the facts and the impressions, reviews and assessments can be included in a separate “quality assessment report” or “occurrence report”, collected in your PSES and reported to the PSO.